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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,279	03/03/2004	Theodor Stern	26041	8931

20529 7590 12/27/2007  
NATH & ASSOCIATES  
112 South West Street  
Alexandria, VA 22314

EXAMINER
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VAKILI, ZOHREH

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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12/27/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/791,279	STERN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zohreh Vakili	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Claims 1-16 are presented for examination.

### ***Status of the Case***

The Amendments and Remarks, filed October 1, 2007, have been received and entered into the application.

Applicant's arguments, filed October 1, 2007, have been fully considered but they are not deemed to be persuasive. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

### ***Maintained Claim Rejections - 35 USC § 103***

The rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Kluger et al. (US PUB. No. 2002/0045873 A1) and in view of Zhao et al. (US Patent No. 6730057 B2) has been maintained for the reasons stated in the prior Office Action June 29, 2007 and further in view of the following remarks.

### ***Response to Arguments***

Applicant argues that Kluger et al. and Zhao et al. do not teach of a formulation or a tampon when inserted is effective in reducing the pH in a menstruating vagina below pH 5.5. Examiner does not agree, Kluger et al. teach of a formulation effective in reducing the pH in a menstruating vagina or in a tampon inserted therein to below pH 5.5, comprising (a) 3-80% by weight of a solid organic acid polymer; (b) 92-15% by weight of a solid organic acid, and (c) 5-30% of a wetting agent. Also disclosed is a delivery system for releasing an active agent comprising: (a) a deposition comprising the active agent; and (b) a polymeric support on which the deposition is deposited, The delivery system is especially useful in a catamenial tampon for insertion in a human vagina which comprises (a) an inner core comprising an absorbent material; (b) an outer layer comprising a liquid permeable material; and (c) the delivery system (see abstract). Examples of solid organic acids are citric, inalic, maleic, fumaric, succinic, tartaric and oxalic acids. A preferred organic acid is citric acid. The organic acid comprises 92-15% of the formulation, and preferably 30-15% (see page 2, paragraph 002). Examples of wetting agents which may be used in the formulation of the invention include glycerol, polyethylene glycol (PEG), polypropylene glycol (PPG) and surfactants with an HLB ranging from 10 to 18. Preferred wetting agents are glycerol and PEG-8000. The wetting agent comprises 5-30% of the formulation, and preferably 5-10% (see page 2, paragraph 0023).

Zhao et al. The flushable tampon applicators of the present invention comprise a

total of from about 1% to about 99%, preferably from about 9% to about 59%, more preferably from about 15% to about 50% of biodegradable thermoplastic polymers by weight of the applicator. The biodegradable thermoplastic polymers can be used individually or as a combination of polymers provided that the biodegradable thermoplastic polymers are degradable by biological and environmental means, and that they are compatible for combination with one or more water-dispersible polymers described hereinabove (see col. 9, lines 25-35). Nonlimiting examples of biodegradable thermoplastic polymers suitable for use in the flushable tampon applicators (see col. 9, lines 48-50). lactide polymers including lactide homopolymers and lactide copolymers; glycolide polymers including glycolide homopolymers and glycolide copolymers; and mixtures thereof. Preferred are aliphatic polyesteramides, diacids/diols aliphatic polyesters, aliphatic/aromatic copolyesters, lactic acid polymers, and lactide polymers (see col. 10, lines 1-10). Preferred aliphatic polyesteramides which are copolymers of aliphatic esters and aliphatic amides can be characterized in that these copolymers generally contain from about 30% to about 70% (see col. 10, lines 24-27). The flushable tampon applicators of the present invention can optionally comprise viscosity modifiers to increase the viscosity of the water-dispersible and biodegradable thermoplastic polymers described herein so that they can be molded using a preferred injection molding or any other molding technique described herein. Such viscosity modifiers are typically included at concentrations ranging from about 0.1% to about 5%, preferably from about 0.1% to about 2% by weight of the applicator. Nonlimiting examples of suitable viscosity modifiers include trifunctional alcohols such

as trimethylolpropane, tetrafunctional alcohols such as pentaerythritol, trifunctional carboxylic acids such as **citric acid**, and the like (see col. 23, lines 28-40).

The characteristics of a compound and its properties are not separated from each other if sodium metabisulphite is known as a decolorizing agent then it is a decolorizing agent no matter with what other ingredients it is used.

Applicant argues that the glycolide used in Zhao et al. formulation has a structural element rather than a functional element. Applicant is reminded that the characteristics of a compound is not separated from its properties. Identical compounds have identical properties and characteristics. If glycolide performs certain functions as Applicant claims therefore, the same functions are apparent in Zhao et al. formulation.

Applicant further discusses each prior art reference separately and not combined with each other. Applicant is reminded that the obviousness rejection is not an anticipation rejection. The Kluger et al. and Zhao et al. references in combination clearly teach formulation or tampon that is effective in reducing the pH in a menstruating vagina. In obviousness rejection a combination of references is used, and the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references that make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the combination of the cited references. *In re Young*, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); *In re Keller* 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Moreover, it is noted that rejections under 35 U.S.C. 103(a) are based on combinations of references, where the secondary references are cited to reconcile the deficiencies of the primary reference with the knowledge generally available to one ordinary skill in the art to show that the differences between Applicant's invention and the prior art are such that they would have been modifications that were *prima facie* obvious to the skilled artisan. It is noted that the claimed invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

For these reasons, and those already made of record at pages 2-5 of the previous Office Action dated June 29, 2007, of which such reasons are incorporated herein by reference, rejection of claims 1-16 remain proper and is **maintained**.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136 (a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 9am to 6:00pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Examiner  
Zohreh Vakili  
Art Unit 1614

December 18, 2007

*Frederick Krass*  
*Primary Examiner*  
*Art Unit 1614*  
